OCT 1 9 2001



[TAB #10]

**Attachment #9**

**Summary of 510(k) Submission**

A. INFORMATION

1. SUBMITTER'S NAME: **TILLOTSON HEALTHCARE CORPORATION**

   ADDRESS: **360 Route 101**
   **Bedford, NH 03110 U.S.A.**

   TELEPHONE NUMBER: **(603) 472-6600**

   CONTACT PERSON: **F.W. Perrella**

   DATE SUMMARY PREPARED: **August 2001**

2. NAME OF DEVICE
   TRADE OR PROPRIETARY NAME: **True Advantage Non-Sterile Powder Free Purple Nitrile Examination Glove**

   COMMON OR USUAL NAME: **Examination Glove**

   CLASSIFICATION NAME: **Examination Glove**

3. PREDICATE DEVICE IDENTIFICATION NAME, NUMBER: **1. Pilgram Nitrile Latex, Non-Sterile Examination Glove K905765A**

4. DESCRIPTION OF DEVICE

   a. HOW THE DEVICE FUNCTIONS:
   **Nitrile films form a barrier to body fluids and bloodborne Pathogens.**

   b. SCIENTIFIC CONCEPTS THAT FORM THE BASIS FOR THE DEVICE:
   **The nitrile rubber is water tight under normal conditions of use. It's tensile Properties cause it to conform to the hand, allowing movements necessary for a medical procedure.**

   c. PHYSICAL AND PERFORMANCE CHARACTERISTICS SUCH AS DESIGN, MATERIALS AND PHYSICAL PROPERTIES:
   **Nitrile Rubber is known to create a barrier to bloodborne pathogens and and body fluids. ASTM D6319 conforming tensile properties create a glove that**

**Is strong and flexible. The leaching process removes traces of chemical accelerants that may be chemically irritating. The glove is manufactured in accordance with the Requirements of ASTM D6319-00 and ASTM D5151-99 requirements.**

5. STATEMENT OF INTENDED USE, INCLUDING DESCRIPTION OF THE DISEASES OR CONDITIONS THAT THE DEVICE WILL ADDRESS

**This is a disposable device, intended for medical purposes, that is worn on the examiner's hand to prevent contamination between patient and examiner. Nitrile Examination gloves are suitable in situations where healthcare worker or patient natural rubber latex allergic sensitivity may be a factor.**

6. EXPLANATION OF SIMILARITIES OR DIFFERENCES TO PREDICATE DEVICE

**The modified product was made powder free and has a color change compared to the predicate product.**

**The modified product has no starch donning powder added, a synthetic inner coating, and a purple color in contrast to the white powdered predicate product claim.**

B. IF THE DECISION BASED ON PERFORMANCE DATA

1. DISCUSSION OF NON-CLINICAL TESTS

| SPECIFICATION | PROPOSED | PREDICATE |
|---|---|---|
| | **Synthetic inner coating with no starch donning powder added and with a purple color claim** | **No synthetic inner coating, but white in color, and with starch donning powder added** |
| PERFORMANCE STANDARDS | **ASTM D6319-00a** | **ASTM D3578-88** |
| WATER TIGHTNESS | **ASTM D5151-99** | **1988 FDA 1000 mL Water Test** |
| ANTIGENIC PROTEIN | **ASTM D6499-00** | |

2. DISCUSSION OF CLINICAL TESTS

| SPECIFICATION | PROPOSED | PREDICATE |
|---|---|---|
| *SAFETY* | | |
| RABBIT IRRITATION | **PASSES** | **PASSES** |
| GUINEA PIG SENSITIZATION | **PASSES** | **PASSES** |

3. CONCLUSIONS DRAWN FROM NONCLINICAL AND CLINICAL TESTS THAT DEMONSTRATE
SAFETY EFFECTIVENESS, AND PERFORMANCE =/> PREDICATE PRODUCT

**The True Advantage Powder Free Purple Nitrile Examination Glove has been carefully compared to legally marketed devices in the 510(k).**
**The data summaries indicate that the proposed product meets or exceeds acceptable scores for the predicate product in nonclinical tests, and satisfies the requirements for a safe and effective, no starch donning powder added with 2 milligrams or less of total particulate purple examination glove claim.**

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**Pursuant to 21 C.F.R. 807.87 ( j ), I, F.W. Perrella, Ph.D., Vice President R&D certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as the V.P. R&D for TILLOTSON HEALTHCARE CORPORATION, and in reliance thereupon, the data and information submitted in this of the substantial equivalence of this device have been knowingly omitted from this Submission.**

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**F.W. Perrella, Ph.D.**
**Vice President R&D**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 9 2001

Mr. Frank W. Perralla, Ph. D.
Vice President, Research and Development
Tillotson Healthcare Corporation
360 Route 101
Bedford, New Hampshire 03110

Re: K013016
Trade/Device Name: True Advantage Non-Sterile Powder Free Purple Nitrile Examination Gloves
Regulation Number: 880.6250
Regulation Name: Examination Gloves
Regulatory Class: I
Product Code: LZA
Dated: August 31, 2001
Received: September 7, 2001

Dear Dr. Perrella:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**3.0 Indications for Use Statement:** Include the following or equivalent Indications for Use page. The information, data and labeling claims in the entire the 510(k) submission must support and agree with the Indications for Use statement.

**INDICATIONS FOR USE**

Applicant: Tillotson Healthcare Corporation

5 10(k) Number (if known):* K013016

Device Name: **True Advantage Non-Sterile Powder Free Purple Nitrile Examination Glove**

Indications For Use:

The **True Advantage Non-Sterile Powder Free Purple Nitrile Patient Examination Glove is "a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.". (21CFR 880.6250).**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH Office of Device Evaluation (ODE)

Clin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013016

Prescription Use _____ OR Over-The-Counter _____
Per 21 CFR 801.109
(Optional Format 1-2-96)

For a new submission, do **NOT** fill in the 510(k) number blank.